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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,917	11/12/1999	PETER J WELCH	P-U-3446	1019

7590 03/22/2002
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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/22/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/438,917

Examiner

Alana M. Harris, Ph.D.

Applicant(s)

WELCH ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation Sheet (PTO-326)

Continuation of Attachment(s) 6). Other: Restriction Election Facsimile Transmission.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to a substantially pure tumor suppressor nucleic acid molecule, SEQ ID NO:2, classified in class 536, subclass 23.1.
- II. Claim 2, drawn to a substantially pure tumor suppressor nucleic acid molecule, SEQ ID NO:18, classified in class 536, subclass 22.1.
- III. Claim 3, drawn to a substantially pure tumor suppressor nucleic acid molecule, SEQ ID NO:5, classified in class 536, subclass 22.1.
- IV. Claim 4, drawn to a substantially pure tumor suppressor nucleic acid molecule encoding SEQ ID NO:6, classified in class 536, subclass 23.5.
- V. Claim 5, drawn to a substantially pure tumor suppressor nucleic acid molecule, SEQ ID NO:4, classified in class 536, subclass 22.1.
- VI. Claim 6, drawn to a substantially pure hairpin ribozyme nucleic acid molecule, SEQ ID NO:1 and SEQ ID NO:3, classified in class 536, subclass 23.2.
- VII. Claim 7, drawn to a substantially pure tumor suppressor polypeptide, SEQ ID NO:6, classified in class 530, subclass 350.
- VIII. Claim 8, drawn to a substantially pure antibody or antigen binding fragment, classified in class 530, subclass 387.1.
- IX. Claim 9, drawn to a method of detecting a neoplastic cell comprising contacting a sample with a detectable agent specific for a tumor suppressor nucleic acid molecule, classified in class 435, subclass 4.

- X. Claim 10, drawn to a method of detecting a neoplastic cell comprising contacting a sample with a detectable agent specific for a tumor suppressor polypeptide, classified in class 436, subclass 63.
2. The inventions are distinct, each from the other because of the following reasons:
- Groups I-VIII are structurally and functionally different products, which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The products of Groups I, V and VI are RNA, ribonucleic acids that function in the biosynthesis of proteins composed of four subunits, whereas the products of Groups II-IV are DNA, deoxyribonucleic acids, unbranched polymers composed of four subunits. However, RNA differs from DNA in that the sugar phosphate backbone contains ribose rather than deoxyribose, it contains the base uracil instead of thymine and it exists as a single strand rather than a double-stranded helix. The polypeptide of Group VII is a linear order of amino acid residues. The antibody product of Group VIII is a glycoprotein.

The methods of Groups IX and X differ in the method objectives, method steps and parameters and in the reagents used.

Inventions of Groups I-V and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each product of Groups I-V can be used in the method of Group IX.

Inventions VIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group VIII can be used in *in vivo* therapy.

3. Group IX is drawn to a method of detecting a neoplastic cell in a sample comprising contacting the sample with an agent specific for a particular tumor suppressor nucleic acid molecule. The polynucleotides that are to be detected are individual, independent and distinct nucleotide sequences, which encode different products. **Thus, with the election of Group IX, the applicant is required to select one of the polynucleotides of Groups I-V that is to be detected for examination.**

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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5. A telephone call was made to David A. Gay on March 18, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.



Alana M. Harris, Ph.D.
March 16, 2002
